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510(k) Summary

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This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92. Information supporting claims of substantial equivalence, as defined under the Federal Food, Drug and Cosmetic Act, respecting safety and effectiveness is outlined below.

Date Prepared: April 12, 2003 **(Revision 1 as of May 26, 2003)**

Name of Submitter:

John E. Sawyer
Realistic Quality Solutions
C/O: GfE Medizintechnik GmbH
6254 South 1280 East
Salt Lake City, Utah 84121
(801) 685-7050

Realistic Quality Solutions has received authorization to submit this 510(k) on behalf of GfE Medizintechnik GmbH

Device Proprietary Name: TiMESH also known as TiMESH-TC

Classification Name: Surgical Mesh per 21 CFR 878.3300

Common/Usual Names:

Mesh, Metallic
Mesh, Non-Metallic
Polypropylene (Absorbable Mesh)
Polypropylene, (Non-Absorbable) Mesh

Predicate Device:

The subject device has the same indications for use as the predicates. The main differences are; changes in the construction of the mesh and the coating of the mesh.

K001122	Prolene Soft Mesh	Ethicon, Inc.
K905655	NonAbsorbable Polypropylene Surgical Mesh	United States Surgical Corp.
K915526	Coated SURGIPRO Polypropylene Surgical Mesh	United States Surgical Corp.

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510(k) Summary (Continued)

Device Description:

TiMESH, also known as TiMESH-TC, hereinafter known as TiMESH/TiMESH-TC" is a non-absorbable polypropylene mesh constructed of warp knitted fabric made from monofilament polypropylene fibers with all around proprietary coating. The TiMESH is constructed using a warp-knit (not woven, not knitted) process.

This construction along with the proprietary coating allows the TiMESH to have the strength, flexibility, as well as durability and surgical adaptability to allow for necessary tissue ingrowth.

The TiMESH with its current construction provides for elasticity in all directions. The construction of the mesh permits the use of any size mesh without it's unraveling. The wetability allows for the proper adaptation of the mesh to various stresses that can be encountered in the body. The product is sterilized by using ethylene oxide gas.

Intended Use:

The TiMESH/TiMESH-TC is specifically indicated for laparoscopic and open surgery for the repair of direct or indirect inguinal, femoral, umbilical, and incisional hernias; rectal, vaginal, and apical prolapses; and parietal reinforcement of tissues and abdominal wall repair. The TiMESH is specifically indicated for open surgery for the repair of direct or indirect inguinal and femoral hernias, pariental reinforcement of tissues, and abdominal wall repair. The TiMESH has the same indications as a combination of the predicate devices. TIMESH is a prescriptive device and should only be used by a licensed physician.

Indications Statement:

The TiMESH/TiMESH-TC The TiMESH, also known as TiMESH-TC, along with Ethicon Inc. Prolene Soft Mesh, U.S.S.C.'s NonAbsorbable Polypropylene Surgical Mesh and Coated SURGIPRO Polypropylene Surgical Mesh are intended to be used for the reinforcement of tissue during surgical repair. Thus, the TiMESH also known as TiMESH-TC mesh and all of the predicates have the same intended use. The TiMESH is specifically indicated for laparoscopic and open surgery for the repair of direct or indirect inguinal, femoral, umbilical, and incisional hernias; rectal, vaginal, and apical prolapses; and parietal reinforcement of tissues and abdominal wall repair.

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510(k) Summary (Continued)

Indications Statement Cont'd:	The TiMESH is specifically indicated for open surgery for the repair of direct or indirect inguinal and femoral hernias, pariental reinforcement of tissues, and abdominal wall repair. The TiMESH has the same indications as a combination of the predicate devices. TIMESH is a prescriptive device and should only be used by a licensed physician.
Technological Characteristics:	GfE Medizintechnik GmbH believes that the subject device is substantially equivalent to the predicate devices. The TiMESH/TiMESH-TC is constructed of the same materials as the predicate devices except for the coating. The Coating process allows the TiMESH to be more flexible than the predicates.
Performance Data:	The patient contact materials used in this device are common materials used in other medical devices as well as the predicate devices and have a long history of biocompatibility. This device complies with the requirements of AAMI/ANSI/ISO 10993, Biological Evaluation of Medical Devices". In addition, bench testing was conducted in accordance with the FDA Guidance Document "Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh".
Conclusions:	Based on the information contained herein, we conclude that the changes are minor and that the subject device is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 9 2003

GfE Medizintechnik GmbH
c/o Mr. John E. Sawyer
President
Realistic Quality Solutions
6254 South 1280 East
Salt Lake City, Utah 84121

Re: K031225
Trade/Device Name: TiMESH also known as TiMESH-TC
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh, polymeric
Regulatory Class: II
Product Code: FTL
Dated: August 8, 2003
Received: August 12, 2003

Dear Mr. Sawyer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K031225

Indications for Use Statement

Applicant: GfE Medizintechnik GmbH

510(k) No. (if known):

Device name: TiMESH also known as TiMESH-TC

Indications for use: The TiMESH, also known as TiMESH-TC, along with Ethicon Inc. Prolene Soft Mesh, U.S.S.C.'s NonAbsorbable Polypropylene Surgical Mesh and Coated SURGIPRO Polypropylene Surgical Mesh are intended to be used for the reinforcement of tissue during surgical repair. Thus, the TiMESH also known as TiMESH-TC mesh and all of the predicates have the same intended use.

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Concurrence of CDRH Office of Device Evaluation (ODE)

Prescription Use ✓ (Per 21 CFR 801.109) OR Over-The-Counter _____ (Optional Format 1-2-96)

Revision: 1 as of May 26, 2003

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative and Neurological Devices

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